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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/802,755	03/09/2001	Seth A. Darst	IPT-012.01	8223

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EXAMINER

GALITSKY, NIKOLAI M

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 06/07/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/802,755

Applicant(s)

DARST ET AL.

Examiner

Nikolai M Galitsky

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). 5.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

Drawings

Applicant is hereby notified that the required timing for the correction of the drawings has changed. See the last 6 lines on the sheet, which is attached, entitled "Attachment for PTO-948 (rev. 03/01 or earlier)". Due to the above notification Applicant is required to submit drawing corrections within the time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant applications or a notice of a failure to fully respond to this Office action.

Group I, claims 1-8, drawn to a crystal of core RNA polymerase complexes with rifampicin at resolution of better than 3.5 Angstroms, classified in Class 530, subclass 350.

Group II, claims 9-11, drawn to a method of identifying an inhibitor of bacterial RNA polymerase by obtaining a set of atomic coordinates of the complex a core RNA polymerase with rifampicin, classified in Class 702, subclass 27. If this group is elected, then the below specie election requirement also is required.

Group III, claims 12-14, drawn to a method of identifying an agent that inhibit the bacterial growth by preparing supplementary crystal containing the core RNA polymerase, classified in Class 702, subclass 27. If this group is elected, then the below specie election requirement also is required.

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Group IV, claims 15-17, drawn a method of identifying an agent that inhibit the bacterial RNA polymerase by preparing a crystal containing the bacterial RNA polymerase, classified in Class 702, subclass 27. If this group is elected, then the below specie election requirement also is required.

Group V, claims 18-20, drawn to a method of identifying an agent that inhibit the bacterial growth by preparing crystal containing the bacterial RNA polymerase, classified in Class 702, subclass 27. If this group is elected, then the below specie election requirement also is required.

Group VI, claims 21-23, drawn to a method obtaining a crystal of an inhibitor bound to a core bacterial RNA polymerase, classified in Class 435, subclass 6.

Group VII, claims 24-26, drawn to a method of identifying a compound that is predicted to inhibit bacterial RNA polymerase, classified in Class 702, subclass 27. If this group is elected, then the below specie election requirement also is required.

Group VIII, claims 27-29, drawn to a method of identifying a compound that is predicted to inhibit bacterial growth, classified in Class 702, subclass 27. If this group is elected, then the below specie election requirement also is required.

Group IX, claim 30, drawn to a computer having the data comprises structural coordinates from Table 2 for displaying 3-D structure complex of Rif-RNA polymerase, classified in Class 702, subclass 27.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Group I and Groups II-IX are related as product and process of use. In the instant case the crystal of Group I is used in alternative inventions of Groups III and V,

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drawn to a method of identifying an agent that inhibit the bacterial growth and a method obtaining a crystal of an inhibitor bound to a core bacterial RNA polymerase, respectively. In addition, the crystal of Group I can be used in a method of molecular replacement in x-ray crystallography to obtain the coordinates of homologous structure, which is also a clearly distinct usage of a molecule or molecular complex coordinates.

Inventions of Groups II- IX are independent. Inventions are independent if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case, the different claimed inventions are independent inventions, each of which have different function, modes of operations and can produce different results.

The method of Group II and III are patentably distinct. The invention of Group II is drawn to a method of identification an agent of bacterial RNA polymerase. The invention of Groups III, drawn to a method of identifying an agent that inhibit the bacterial growth. The inventions of these Groups have different functions, different effects, and different modes of operation.

The method of Group II and IV are patentably distinct. The invention of Group II is drawn to a method of identification an agent of bacterial RNA polymerase. The invention of Groups IV, drawn to a method of identifying an agent that inhibit the bacterial RNA polymerase. The inventions of these Groups have different functions, different effects, and different modes of operation.

The method of Group II and V are patentably distinct. The invention of Group II is drawn to a method of identification an agent of bacterial RNA polymerase. The invention of Groups V, drawn to a method of identifying an agent that inhibit the bacterial growth. The inventions of these Groups have different functions, different effects, and different modes of operation.

The method of Group II and VI are patentably distinct. The invention of Group II is drawn to a method of identification an agent of bacterial RNA polymerase. The invention of Groups VI, drawn to a method obtaining a crystal of an inhibitor bound to a core bacterial RNA polymerase. The inventions of these Groups have different functions, different effects, and different modes of operation.

The method of Group II and VII are patentably distinct. The invention of Group II is drawn to a method of identification an agent of bacterial RNA polymerase. The invention of Groups VII, drawn to a method of identifying a compound that is predicted to inhibit bacterial RNA polymerase. The inventions of these Groups have different functions, different effects, and different modes of operation.

The method of Group II and VIII are patentably distinct. The invention of Group II is drawn to a method of identification an agent of bacterial RNA polymerase. The invention of Groups VIII, drawn to a method of identifying a compound that is predicted to inhibit bacterial growth. The inventions of these Groups have different functions, different effects, and different modes of operation.

The inventions of Groups II and IX are patentably distinct. The invention of Group II is drawn to a method of identification an agent of bacterial RNA polymerase. The invention of Groups IX, drawn to a computer having the data comprises structural coordinates. The

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inventions of these Groups have different functions, different effects, and different modes of operation.

The inventions of Groups III and IV are separate and non-overlapping in that inhibition bacterial growth of Group III lacks any result determination of the what actually inhibited etc. the bacterial target which is, however, the central issue in Group IV with also a inhibition of the bacterial RNA polymerase determination which is also not needed for the Group III inhibition etc.

The inventions of Group III and Group V are related as distinct methods of identifying an agent that inhibit the bacterial growth. The method of Group III practices a crystal containing the core RNA polymerase, whereas the method of Group V practices a crystal containing the bacterial RNA polymerase.

The method of Group III and VI are patentably distinct inventions. The invention of Group III is drawn to a method of identifying an agent that inhibit the bacterial growth. The invention of Groups VI, drawn to a method obtaining a crystal of an inhibitor bound to a core bacterial RNA polymerase. The inventions of these Groups have different functions, different effects, and different modes of operation.

The method of Group III and VII are patentably distinct inventions. The invention of Group III is drawn to a method of identifying an agent that inhibit the bacterial growth. The invention of Groups VII, drawn to a method of identifying a compound that is predicted to inhibit bacterial RNA polymerase. The inventions of these Groups have different functions, different effects, and different modes of operation.

The method of Group III and VIII are patentably distinct inventions. The invention of Group III is drawn to a method of identifying an agent that inhibit the bacterial growth. The invention of Groups VIII, drawn a method of identifying a compound that is predicted. The inventions of these Groups have different functions, different effects, and different modes of operation.

The inventions of Groups III and IX are separate and patentably distinct inventions. The invention of Group III is drawn to a method of identifying an agent that inhibit the bacterial growth. The invention of Groups IX, drawn to a computer having the data comprises structural coordinates. The inventions of these Groups have different functions, different effects, and different modes of operation.

The method of Group IV and V are patentably distinct. The invention of Group IV is drawn to a method of identification an agent of bacterial RNA polymerase. The invention of Groups V, drawn to a method of identifying an agent that inhibit the bacterial growth. The inventions of these Groups have different functions, different effects, and different modes of operation.

The method of Group IV and VI are patentably distinct. The invention of Group IV is drawn to a method of identification an agent of bacterial RNA polymerase. The invention of Groups VI, drawn to a method obtaining a crystal of an inhibitor bound to a core bacterial RNA polymerase. The inventions of these Groups have different functions, different effects, and different modes of operation.

The method of Group IV and VII are patentably distinct. The invention of Group II is drawn to a method of identification an agent of bacterial RNA polymerase. The invention of

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Groups VII, drawn to a method of identifying a compound that is predicted. The inventions of these Groups have different functions, different effects, and different modes of operation.

The method of Group IV and VIII are patentably distinct. The invention of Group IV is drawn to a method of identification an agent of bacterial RNA polymerase. The invention of Groups VIII, drawn to a method of identifying a compound that is predicted to inhibit bacterial growth. The inventions of these Groups have different functions, different effects, and different modes of operation.

The inventions of Groups IV and IX are patentably distinct. The invention of Group IV is drawn to a method of identification an agent of bacterial RNA polymerase. The invention of Groups IX, drawn to a computer having the data comprises structural coordinates. The inventions of these Groups have different functions, different effects, and different modes of operation.

The method of Group V and VI are patentably distinct. The invention of Group V is drawn to a method of identification an agent of bacterial RNA polymerase. The invention of Groups VI, drawn to a method obtaining a crystal of an inhibitor bound to a core bacterial RNA polymerase. The inventions of these Groups have different functions, different effects, and different modes of operation.

The method of Group V and VII are patentably distinct inventions. The invention of Group V is drawn to a method of identifying an agent that inhibit the bacterial growth. The invention of Groups VII, drawn to a method of identifying a compound that is predicted to inhibit bacterial RNA polymerase. The inventions of these Groups have different functions, different effects, and different modes of operation.

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The method of Group V and VIII are patentably distinct inventions. The invention of Group V is drawn to a method of identifying an agent that inhibit the bacterial growth. The invention of Groups VIII, drawn a method of identifying a compound that is predicted. The inventions of these Groups have different functions, different effects, and different modes of operation.

The inventions of Groups V and IX are separate and patentably distinct inventions. The invention of Group V is drawn to a method of identifying an agent that inhibit the bacterial growth. The invention of Groups IX, drawn to a computer having the data comprises structural coordinates. The inventions of these Groups have different functions, different effects, and different modes of operation.

The method of Group VI and VII are patentably distinct inventions. The invention of Group VI is drawn a method obtaining a crystal of an inhibitor bound to a core bacterial RNA polymerase. The invention of Groups VII, drawn to a method of identifying a compound that is predicted to inhibit bacterial RNA polymerase. The inventions of these Groups have different functions, different effects, and different modes of operation.

The method of Group VI and VIII are patentably distinct. The invention of Group VI is drawn to a method obtaining a crystal of an inhibitor bound to a core bacterial RNA polymerase. The invention of Groups VIII, drawn to a method of identifying a compound that is predicted to inhibit bacterial growth. The inventions of these Groups have different functions, different effects, and different modes of operation.

The inventions of Groups VI and IX are separate and patentably distinct inventions. The invention of Group VI is directed to obtain a crystal of an inhibitor bound to a core bacterial

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RNA polymerase, whereas the invention of Groups IX, drawn to a computer having the data comprises structural coordinates. The inventions of these Groups have different functions, different effects, and different modes of operation.

The method of Group VII and VIII are patentably distinct. The invention of Group VII is drawn to a method of identifying a compound that is predicted to inhibit bacterial RNA polymerase. The invention of Groups VIII, drawn to a method of identifying a compound that is predicted to inhibit bacterial growth. The inventions of these Groups have different functions, different effects, and different modes of operation.

The inventions of Groups VII and IX are separate and patentably distinct inventions. The invention of Group VII is drawn a method of identifying a compound that is predicted to inhibit bacterial RNA polymerase, whereas the invention of Groups IX, drawn to a computer having the data comprises structural coordinates. The inventions of these Groups have different functions, different effects, and different modes of operation.

The inventions of Groups VIII and IX are separate and patentably distinct inventions. The invention of Group VIII is drawn a method of identifying a compound that is predicted to inhibit bacterial growth, whereas the invention of Groups IX, drawn to a computer having the data comprises structural coordinates. The inventions of these Groups have different functions, different effects, and different modes of operation.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because the products or methods of groups I-IX constitute patentably distinct inventions.

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SPECIE ELECTION REQUIREMENT FOR GROUPS II-V and VII-VIII:

This application contains claim directed to the following patentably distinct species of the claimed invention: The species of Groups III, V, and VIII are distinct because they each add a feature to the method of identifying of compounds with different and distinct functions; the species of Groups II, IV, and VII are distinct from each other because they are independent, using structural and functionally different compounds, which each would require a separate and burdensome search to add to the search for the basic detection compounds as defined above.

Groups III, V, and VIII:

Specie A: a bacterial RNA polymerase utilized only;

Specie B: an eukaryotic RNA polymerase.

Groups II, IV, and VII:

Specie C: a bacterial culture;

Specie D: an eukaryotic cell;

Applicants are advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, the specie elections for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikolai Galitsky, Ph.D., whose telephone number is (703) 308-2422. The examiner can normally be reached on Monday-Friday from 8:30 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Bill Phillips, whose telephone number is (703) 305-3482 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

May 30, 2002

NMG


ARDIN H. MARSCHEL
PRIMARY EXAMINER